

REMARKS

The Office Action has been carefully reviewed. Claim 1 is allowed. Claims 59-69 presently appear in the present application, with new dependent claim 60 being equivalent in scope to allowed claim 1, and define patentable subject matter warranting their allowance. Reconsideration and allowance are hereby respectfully solicited.

Claims 9 and 13 have been rejected under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. This rejection is obviated by the cancellation of rejected claims 9 and 13 without prejudice. This written description rejection is discussed below insofar as it might relate to new claims 59-69.

The examiner's attention is respectfully drawn to the USPTO's "Synopsis of Application of Written Description Guidelines" (previously "Revised Interim Written Description Guidelines Training Materials") and, particularly, Example 14: "Product by Function." In that example, the specification exemplified a protein isolated from liver that catalyzed the reaction of A→B, which isolated protein was sequenced and was determined to have the sequence as set forth in SEQ ID NO:3. The specification also contemplated, but did not exemplify, variants of the protein wherein the variant can have any or all of the following: substitutions, deletions, insertions, and additions. The specification indicated that procedures for making proteins with substitutions, deletions, insertions, and additions is routine in the art and provided an assay for detecting the catalytic activity of the protein.

This description in the specification is very similar to the description which appears in the present specification. The present specification exemplifies a non-reducing saccharide-forming enzyme. The sequence of this enzyme is specified (SEQ ID NO:1). The present specification also indicates that procedures for making proteins with substitutions, deletions, insertions, and additions (see, for example, pages 14-22 of the present specification) and provides an assay for determining whether a given protein has the catalytic activity of a non-reducing saccharide forming enzyme (see paragraph bridging pages 12 and 13 of the present specification).

In Example 14 of the Synopsis of Application of Written Description Guidelines, the claim is directed to:

A protein having SEQ ID NO:3 and variants thereof
that are at least 95% identical to SEQ ID NO:3
and catalyze the reaction of A→B.

The present claim 59 is drawn to a protein/enzyme having effectively at least 80% identity with the sequence of SEQ ID NO:1 and has the ability to form non-reducing saccharide or a fragment (deletion) of the enzyme comprising SEQ ID NO:1. The enzyme as recited as a Markush group has the catalytic activity of forming a non-reducing saccharide having a trehalose structure as an end unit from a reducing partial starch hydrolysate and an optimum temperature of over 40°C but below 60°C.

The analysis in the Synopsis of Application of Written Description Guidelines acknowledges that procedures for making variants of SEQ ID NO:3 are conventional in the art and that an assay is described which will identify other proteins having the claimed functionality. Moreover, procedures for making variants of SEQ ID NO:3

which have 95% identity to SEQ ID NO:3 and retain its activity were conceded as being conventional in the art. It would, of course, be understood that procedures for making variants of the enzyme of (A) of claim 59, which have 80% identity to that sequence and retain its catalytic activity for forming a non-reducing saccharide from a reducing partial starch hydrolysate are also conventional in the art.

The analysis goes on to point out that all variants of the claim must possess the specified catalytic activity and must have at least 95% identity to the SEQ ID NO:3. Furthermore, because of the "having" language, the protein claimed may be larger than SEQ ID NO:3 or its variant with 95% identity to SEQ ID NO:3. The analysis points out that the specification contains a reduction to practice of the single disclosed species. The analysis concludes:

The specification indicates that the genus of proteins that must be variants of SEQ ID NO:3 does not have substantial variations since all the variants must possess the specified catalytic activity and must have at least 95% identity to the reference sequence, SEQ ID NO:3. The single species disclosed is representative of the genus because all members have at least 95% structural identity with the reference compound and because of the presence of an assay which applicant provided for identifying all of the at least 95% identical variants of SEQ ID NO:3 which are capable of the specified catalytic activity. One of skill in the art would conclude that applicant was in possession of the necessary common attributes possessed by the members of the genus.

Conclusion: The disclosure meets the requirements of 35 U.S.C. §112, first paragraph, as providing adequate written description for the claimed invention.

Thus, it is apparent that if the single species disclosed is representative of the genus and an assay is present for identifying the

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members of the variants that are capable of the specified functionality, the written description requirement is met. Here, the 80% identity is less than the 95% identity that was found to satisfy the written description guidelines, but applicants submit that such at least 80% sequence identity is close enough to 95% (still high homology) to also satisfy the USPTO written description guidelines.

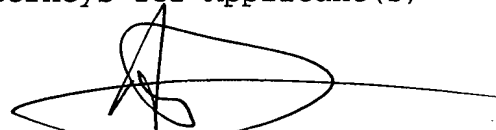
Accordingly, the USPTO's Synopsis of Application of Written Description Guidelines clearly indicate that the present claims satisfy the written description requirement.

In view of the above, the claims comply with 35 U.S.C. §112 and define patentable subject matter warranting their allowance. Reconsideration and early allowance are earnestly urged.

Respectfully submitted,

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